

LEWIS BRISBOIS BISGAARD & SMITH, LLP

Malinda A. Miller, Esq.

NJ Attorney ID #: 020691996

S. Christopher Marino, Esq.

NJ Attorney ID #076692013

One Riverfront Plaza

1037 Raymond Blvd., 8th Floor

Newark, New Jersey 07102

Tel: (973) 577-6260

Fax: (973) 577-6261

Attorneys for Defendants, Alliance HC Holdings, LLC d/b/a Andover Subacute & Rehabilitation I; Alliance HC II LLC d/b/a Andover Subacute & Rehabilitation II (Alliance Healthcare being improperly pleaded by name and as a separate entity); Chaim “Mutt” Scheinbaum; Louis Schwartz

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ESTATE OF JOSEPH MAGLIOLI, BERNARD
MAGLIOLI and DANTE MAGLIOLI, and
ESTATE OF DALE PETRY and
CHRISTOPHER PETRY,

Plaintiffs,

v.

ANDOVER SUBACUTE REHABILITATION
CENTER I; ANDOVER SUBACUTE
REHABILITATION CENTER II; ALTITUDE
HEALTH SERVICES INC.; ALTITUDE
INVESTMENTS, LTD; ALLIANCE
HEALTHCARE; CHAIM “MUTTY”
SCHEINBAUM; LOUIS SCHWARTZ;
HEALTHCARE SERVICES GROUP; JOHN
AND JANE DOES 1-10; and ABC AND XYZ
Corporations 1-10,

Defendants.

Civil Action No.:

**NOTICE OF REMOVAL OF CIVIL ACTION
PURSUANT TO 28 U.S.C. §§ 1331, 1441,
1442(a)(1) and 1446**

TO: Clerk of Court
United States District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

WITH NOTICE TO:
Daniel P. Marchese, Esq.
The Marchese Law Firm, LLC
93 Spring Street, Suite 300
Newton, NJ 07860

Neil Lapinski, Esq.
William Kelleher, Esq.
Phillip Giordano, Esq.
Gordon, Fournaris & Mammarella, P.A.
1925 Lovering Avenue
Wilmington, DE 19806
Counsel to Plaintiffs

PLEASE TAKE NOTICE THAT Defendants, Alliance HC Holdings, LLC d/b/a Andover Subacute & Rehabilitation I; Alliance HC II LLC d/b/a Andover Subacute & Rehabilitation II (Alliance Healthcare being improperly pleaded by name and as a separate entity); Chaim “Mutt” Scheinbaum; Louis Schwartz (collectively “Defendants”), hereby remove to this District Court the state action currently pending in the Sussex County Superior Court of New Jersey pursuant to 28 U.S.C. §§ 1331, 1441, 1442(a)(1), and 1446 described more fully below.

INTRADISTRICT ASSIGNMENT

The United States District Court for the District of New Jersey embraces the district and division in which the Sussex County, New Jersey state court action is now pending, and thus this Court is a proper venue for the action pursuant to 28 U.S.C. § 110.

PLEADINGS & PROCEDURAL HISTORY

1. On or about April 28, 2020, Plaintiffs filed a Complaint in the Superior Court of the State of New Jersey in and for the County of Sussex entitled, Estate of Joseph Maglioli, Bernard Maglioli and Dante Maglioli v. Andover Subacute Rehabilitation Center I, et al. as Docket No. SSX-L-176-20. The suit named the aforementioned Plaintiffs as well as “others similarly situated” as part of a purported Class Action. **See attached hereto as Exhibit A, a true and accurate copy of the Complaint filed on April 28, 2020.**
2. On or about May 18, 2020, a First Amended Complaint was filed in the Superior Court of New Jersey, amending the action to name additional named Plaintiffs, including the Estate of Dale

Petry and Christopher Petry. **See attached hereto as Exhibit B, a true and accurate copy of the First Amended Complaint filed on May 18, 2020.**

3. On or about May 26, 2020, a Second Amended Complaint was filed in the Superior Court of New Jersey, amending the action to identify an additional Defendant, Healthcare Services Group.

See attached hereto as Exhibit C, a true and accurate copy of the Second Amended Complaint filed on May 26, 2020.

4. Plaintiffs' allegations arise exclusively from the outbreak of the COVID-19 virus in the winter/spring of 2020 and Defendants' alleged negligence in the manner in which they allocated and implemented countermeasures in responding to the global COVID-19 pandemic and rendering treatment to Plaintiffs' decedents while they were residing at Defendants' facilities. Specifically, plaintiffs allege that "Defendants breached their duty" "to prevent the spread of the Covid-19 virus" in negligently executing "proper protocols and procedures" "for the prevention of the spread of the Covid-19 virus" and negligently allocating and misusing "personal protective equipment" and other equipment at the facilities. **See Exhibit C, ¶ 14, 28, 32 & 36.**
5. Paragraph 14 specifically alleges the misuse and allocation of personal protective equipment and criticizes distribution plans which provided equipment to certain staff and not others by Defendants:

14. Evidently, at first, Defendants' **management provided masks only to registered nurses, not to others who also interacted with residents**, including housekeepers, recreation therapists and nursing assistants, among other potential miscues.

6. On or about May 29, 2021, Defendants timely filed a Notice of Removal in the United States District Court for the District of New Jersey, asserting federal jurisdiction under the PREP Act, the Grable doctrine, and pursuant to the Federal Officer Removal Statute. See Estate of Maglioli v. Andover Subacute and Rehabilitation I, et al., 2:20-cv-06605-KM-ESK. **See attached hereto**

as Exhibit D, a true and accurate copy of the ECF Docket Report for 2:20-cv-06605-KM-ESK.

7. More specifically, Defendants removed because the conduct alleged in the Complaint invokes the use or administration of “covered countermeasures” arising under the PREP Act and, thus, the PREP Act confers federal jurisdiction by complete preemption. Moreover, a substantial federal interest warrants federal jurisdiction in this matter. Finally, the actions by Defendants were taken at the specific direction and oversight of the federal government, thus warranting removal under the Federal Officer Removal Statute.¹
8. On August 12, 2020, the Court granted Plaintiffs’ motion to remand finding: 1) the PREP Act is not a complete preemption statute; 2) the PREP Act is only applicable to the actual use or physical administration of a “covered countermeasure”; and 3) Defendants were not entitled to removal under the Federal Officer Removal Statute 42 U.S.C. § 1442(a)(1) because they failed to meet the requirement that they were “acting under” a federal officer or agency. At the time of the remand, federal law governing the PREP Act’s application in the context of the COVID-19 pandemic was still undeveloped.²
9. Since the remand order was entered, the United States Health and Human Services (“HHS”) issued new controlling authority, Advisory Opinion 21-01 (“AO 21-01”), on January 8, 2021, which confirms unequivocally that: 1) the PREP Act is indeed invoked by allegations like those in the Complaint, including alleged failure to act or inaction; 2) the PREP Act is a “Complete Preemption” Statute which confers federal question removal jurisdiction under 28 U.S.C. § 1441(a); and 3) federal jurisdiction is separately conferred in such cases under the doctrine

¹ In filing this Notice of Removal herein, Defendants do not waive or withdraw any prior bases for their initial removal, which bases are currently on review before the United States Court of Appeals for the Third Circuit.

² On September 9, 2020, Defendants filed a Notice of Appeal to the United States Court of Appeals for the Third Circuit relating to the Court’s remand order. This Appeal is pending under the docket Nos. 20–2833 & 20–2834.

articulated by the United States Supreme Court in Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308 (2005), because “ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court.”³

10. Significantly, AO 21-01 expounded on the Fourth Amendment Declaration, which had declared that an omission or failure to administer a Covered Countermeasure can fall within the PREP Act’s protections, and AO 21-01 clarified purported ambiguities particularly in the context of nursing homes and other health facilities. Advisory Opinion 21-01 states:

These inquiries were stimulated, as we understand, by a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment (“PPE”), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given.

11. The Advisory Opinion clearly articulates that the PREP Act is a “Complete Preemption Statute” and further notes that some district courts have incorrectly interpreted the scope of the immunity in subparagraph (B) as requiring “use.” The Advisory Opinion rejects Lutz v. Big Blue Healthcare, Inc., 2020 WL 4815100, at *8 (D. Kan. 2020), where, in remanding the case to state court, the Court held “[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of a covered countermeasure.”
12. AO 21-01 holds that a “black and white” view regarding “use” of a covered countermeasure clashes with the plain language of the PREP Act, which extends immunity to anything “relating to” the administration of a covered countermeasure. The Opinion further directs that

³ HHS, Office of the General Counsel, “Advisory Opinion No. 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision” (Jan. 8, 2021), *available at* <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

“prioritization or purposeful allocation of a covered countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act.”

13. The Advisory Opinion goes on to clarify that “decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning” and thus is expressly covered by the PREP Act.

14. In addition to these HHS authorities, the U.S. Department of Justice (“DOJ”) filed a Statement of Interest (“SOI”) on behalf of the United States in Bolton v. Gallatin Center for Rehabilitation, LLC, No. 3:30-cv-00683 (M.D. Tenn. Jan. 19, 2021), which sets for the official position of the United States with respect to the enforcement of the PREP Act providing, *inter alia*, that:

a. The District Court’s interpretation of the PREP Act in Maglioli and subsequent cases regarding the preemptive effect was incorrect, and that its holding should be limited to the facts.

b. Federal jurisdiction is proper since the PREP Act’s exclusive federal cause of action creates federal question jurisdiction.

c. The PREP Act is crucial to a “whole-of-nation response to public health emergencies. This response depends on coordination among private sector partners and state and local officials across the nation and that “sweeping” immunity was granted to encourage such cooperation.

d. The nature of the complaint determines preemption, not the state claims.

See attached hereto as Exhibit E, Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, No. 3:20-cv-00683, Doc. 35-1, Statement of Interest of the United States (M.D. Tenn. Jan. 19, 2021).

15. Subsequent to these directives, in Garcia v. Welltower OpCo Group LLC, No. 8:20-cv-02250-JVS-KESx (C.D. Cal), the District Court for the Central District of California concluded that the

PREP Act was applicable to a plaintiffs' claims for negligence similar to those alleged herein. In denying plaintiffs' motion to remand, the Court relied on AO 21-01 and concluded, among other things, that "because the OGC stated the PREP Act is a complete preemption statute...an adequate bases for federal question jurisdiction exists."

16. Based upon this new controlling authority which unequivocally confers federal jurisdiction to the underlying claims, Defendants hereby remove this matter to the United States District Court for the District of New Jersey.

REMOVAL IS PROPER BASED ON 28 U.S.C. 1446(b)(3)

17. Defendants' removal is timely under 28 U.S.C. § 1446(b)(3) as it is being filed within 30 days of receipt by Defendants of "Advisory Opinion 21-01 on The Public Readiness and Emergency Preparedness Act Scope of Preemption Provision" dated January 8, 2021.
18. A "notice of removal may be filed within 30 days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446(b)(3). The defendant bears the burden of proof regarding the propriety of removal, and we resolve all doubts in favor of remand. Steel Valley Auth. v. Union Switch & Signal Div., 809 F.2d 1006, 1010 (3d Cir. 1987).
19. AO 21-01 qualifies as "other paper" pursuant to 1446(b) and provided Defendants with their first opportunity to file the present removal because it, for first time, establishes with clear and unambiguous language that federal jurisdiction should be conferred in the present matter.
20. District Courts within the Third Circuit interpret the phrase "other paper" widely... " Nicole B. v. Sch. Dist. of Phila., 2016 U.S. Dist. LEXIS 79650, at *6-7 (E.D. Pa. June 14, 2016) (citing Minissale v. State Farm Fire & Cas. Co., 988 F. Supp. 2d 472, 477 (E.D. Pa. 2013); see also Connolly v. Aetna U.S. Healthcare, Inc., 286 F.Supp.2d 391, 399 (D.N.J. 2003); Efford v.

Milam, 368 F.Supp.2d 380, 386 (E.D. Pa. 2005); Cabibbo v. Einstein/Noah Bagel Partners, L.P., 181 F.Supp.2d 428, 432-33 (E.D. Pa. 2002).

21. Moreover, successive removals are permitted in other federal jurisdictions when, as here, there is a change in circumstance or the law itself. For example, in the 9th Circuit, a successive removal petition is permitted upon a “relevant change of circumstance” – that is, “when subsequent pleadings or events reveal new and different grounds for removal.” Kirkbride v. Cont’l Cas. Co., 933 F.2d 729 (9th Cir. 1991); see Reyes v. Dollar Tree Stores, Inc., 781 F.3d 1185 (9th Cir. 2015). “An intervening change in the law that ‘gives rise to a new basis for subject matter jurisdiction’ qualifies as a subsequent event that justifies a successive removal petition.” Fritsch v. Swift Transportation Company of Arizona, LLC, 899 F.3d 785, 780 (9th Cir. 2018); See also Rea v. Michaels Stores, Inc., 742 F.3d 1234, 1238; Kirkbride, 933 F.2d at 732.
22. Furthermore, courts have looked to “other paper” to establish federal question jurisdiction, such as to clarify that a plaintiff’s state law claim is one that would be preempted by federal law. Eggert v. Britton, 223 Fed. Appx. 394, 397 (5th Cir. 2007).
23. For example, in Peters v. Lincoln Elec. Co., 285 F.3d 456, 468-69 (6th Cir. 2002), the Sixth Circuit permitted the examination of deposition testimony to ascertain that the plaintiff’s state law claim was related to his retirement plan and was, therefore, preempted by ERISA. The Sixth Circuit discussed that complete preemption is an exception to the well-pleaded complaint rule and concluded that federal question jurisdiction was proper. Id at 468-469.
24. Defendants filed an initial Notice of Removal on or about May 29, 2020. Defendants contended at that time, as they do now, that they are immune from liability under the federal PREP Act and that application of the PREP Act completely preempts state law and confers exclusive federal jurisdiction. Defendants also argued that federal jurisdiction was appropriate insofar as the applicability of the PREP Act to the matter herein turned on a substantial question of federal

law in which “a federal court ought to be hear” See Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308 (2005). Lastly, Defendants argued that federal jurisdiction was appropriate under the Federal Officer Removal Statute.

25. The District Court’s decision granting Plaintiffs’ motion to remand was decided on or about August 12, 2020.

26. While multiple authorities subsequent to the Court’s decision are important and must be read together, the January 8, 2021 Advisory Opinion is the critical authority permitting the Notice of Removal herein. The Advisory Opinion provided the first official confirmation from the Secretary that the PREP Act is a complete preemption statute. This has since been confirmed by the Fifth Amendment to the Declaration.

27. Furthermore, AO 21-01 is binding on this Court, as the HHS Secretary incorporated all HHS Advisory Opinions pertaining to COVID-19 into the PREP Act’s implementing Declaration itself, and proclaimed that the Declaration “must” be construed in accordance with them. See Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190 (Dec. 9, 2020) (the “Fourth Amendment” or “Amendment”). The Fourth Amendment incorporated all HHS Advisory Opinions into the Declaration itself, thus giving them controlling weight. 85 Fed. Reg. 79190. As such, the HHS Advisory Opinions are no longer “advisory,” they now have the same “controlling weight” as the Declaration and the PREP Act itself. Where Congress has expressly delegated interpretative authority to an agency, that agency’s interpretative proclamations are controlling on the federal courts. See Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 843-44 (1984). Also, Congress reinforced the Secretary’s ultimate authority over these matters concerning the PREP Act in the statute itself, warning that “[n]o court . . . shall have subject matter jurisdiction to review, whether by mandamus or

otherwise, any action by the Secretary under [the PREP Act.]” 42 U.S.C. § 247d-6d(b)(1), (4) & (7).

28. Furthermore, Advisory Opinion 21-01 is binding on this court, as the HHS Secretary has now incorporated all HHS Advisory Opinions pertaining to COVID-19 into the PREP Acts implementing Declaration itself, and proclaimed that the Declaration “must” be construed in accordance with them. As such, the HHS Advisory Opinions are no longer “advisory” and have the same “controlling weight” as the Declaration and the PREP Act itself. Where Congress has expressly delegated interpretative authority to an agency, that agency’s interpretive proclamations are controlling on federal courts. See Chevron, U.S.A., Inc. v NRDC, Inc., 467 U.S. 837, 843044 (1984).

29. Also, to avoid any doubt, the Secretary thereafter amended the Declaration a fifth time on January 28, 2021, confirming again in the Declaration itself that the PREP Act is a complete preemption statute. After adding additional categories of qualified persons, such as vaccinators, to be covered under PREP Act immunity, the Fifth Amendment concludes “[t]he plain language of the PREP Act makes clear that there is complete preemption of State law” and that “preemption of State law is justified to respond to the nationwide public health emergency caused by COVID-19. . . .” 86 Fed. Reg. 7872, at 7874.

30. Based on this new and controlling authority from HHS, Defendant hereby removes this case to the United States District Court for the District of New Jersey.

JURISDICTION EXISTS UNDER 28 U.S.C. § 1331 (FEDERAL QUESTION)

I. PLAINTIFFS’ CLAIMS ARE COVERED BY THE PREP ACT

31. The Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d 6d, 247d-6e(2006) and the Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020) (together, the PREP Act”) are federal statutes that apply specifically to medical

providers such as Defendants in the administration of countermeasures to prevent or mitigate the spread of COVID-19.

32. Under the PREP Act, 42 U.S.C. §§ 247d-6d and 247d-6e (2006), Congress has provided immunity for claims, as well as exclusive federal jurisdiction for the allegations and relief sought in Plaintiffs' Second Amended Complaint. This legislation empowers the Secretary of Health and Human Services to issue a declaration providing immunity for "covered persons" to suits and liability under federal and state law relating to the administration of a "Covered Countermeasure" during a health emergency.

33. Specifically, 42 U.S.C. §247d-6d(a)(1) provides as follows: "Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a Covered Countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." Section (b) of the PREP Act provides that if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes as public health emergency, the Secretary may make a declaration setting forth that subsection (a) is in effect with respect to the manufacture, testing, development, distribution, administration or use of one or more Covered Countermeasures under conditions as the Secretary may specify in the Declaration or an amendment thereto. 42 U.S.C. § 247d-6d(b)(1) and (4).

a. Defendants qualify as Covered Persons under the PREP Act

34. Pursuant to the Act, a "covered person" includes (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) program planners; and (iv) qualified persons who prescribe, administer or dispense covered countermeasures. 42 U.S.C. § 247d-6d(i)(2).

35. “Qualified persons” include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other persons identified in a declaration by the Secretary. 42 U.S.C. § 247d-6d(i)(8).

36. “Program planners” include state and local governments or other persons who supervise or administer programs that dispense, distribute, or administer covered countermeasures, *or* provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. 42 U.S.C. § 247d-6d(i)(6).

37. The meaning of other “program planner” and “qualified person” has been clarified as follows:

...State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary’s declaration].

42 U.S.C. § 247d-6d[i][6].

38. Under the Secretary’s declaration, “[A] **private sector employer or community group or other ‘person’ can be a program planner when it carries out the described activities.**” 85 Fed. Reg. at 15,202.

39. Furthermore, on August 14, 2020, the Office of General Counsel confirmed that senior living communities are “covered persons” subject to immunity under the PREP Act as “program planners” and “qualified persons.” [OGC Letter to Thomas Barker.] The Office of General Counsel also published a Guidance confirming that COVID testing in nursing homes is a covered countermeasure triggering the Act.⁴

⁴ HHS, Office of the General Counsel, Letter to Thomas Barker, Foley Hoag LLP (Aug. 14, 2020) *available at* <https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf> [Aug. 31, 2020].

40. On October 23, 2020, the Office of the General Counsel’s Advisory Opinion No. 20-04 verified that the term “program planner” is broadly defined.⁵ The opinion also explained that PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with any public health guidance from an “Authority Having Jurisdiction.”
41. The January 8, 2021 Advisory Opinion 21-01 more broadly outlined that a “program planner” under the Act is “someone who is involved in providing or allocating covered countermeasures,” and that “program planning inherently involves the allocation of resources.” The Advisory Opinion thereby concluded that **“decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by [the] PREP Act.”**
42. Defendants qualify as “covered persons” under the PREP Act.
43. During the time set forth in the underlying Complaint, Defendants acted as both “qualified persons” and “program planners.” Defendants Alliance HC Holdings, LLC d/b/a Andover Subacute & Rehabilitation I and Alliance HC II LLC d/b/a Andover Subacute & Rehabilitation II operated as skilled nursing facilities licensed by the New Jersey Department of Health. The claims regarding Defendants Chaim “Muttu” Scheinbaum and Louis Schwartz, whom are being sued in their respective capacities as owners, are derivative to those directed at the two nursing facility Defendants.
44. Defendants employed various medical professionals including administrators, directors, nursing personnel, physicians, therapists, and nursing aides who were authorized to allocate, administer, prescribe, and dispense the covered countermeasures set forth in Plaintiffs’ Complaint, including

⁵ HHS, Office of the General Counsel, “Advisory Opinion No. 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration Under the Act” (Oct. 22, 2020, as modified Oct. 23, 2020), *available at* (https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf) [Advisory Opinion 20-04.]

PPE such as facemasks, gloves, gowns, face shields, N95 masks, COVID testing materials, thermometers, and other items which qualify as pandemic or epidemic products). Additionally, these individuals developed, administered, and oversaw policies, procedures, and programs related to infection control.

b. The PREP Act is triggered because Plaintiffs' claims arise from the Defendants use and administration of "Covered Countermeasures."

45. The PREP Act is applicable with respect to a "covered countermeasure," which by definition includes: "(1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i)(7)) . . . or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Health and Human Service Secretary determines to be a priority for use during a public health emergency declared under section 247d." 42 U.S.C. § 247d-6d(i)(1). A "qualified pandemic or epidemic product" is defined as: a drug, biologic product or device that is:

"(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

- (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
- (II) to limit the harm such pandemic or epidemic might otherwise cause;
- (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i); or
- (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
- (B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
- (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
- (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act."

See 42 U.S.C. § 247d-6d(i)(7).

46. The March 17, 2020 Declaration expanded the categories of "covered countermeasures" eligible for immunity to include *any* device used to treat, diagnose, cure, prevent or mitigate COVID-19

or its spread. The Declaration was subsequently amended to add respiratory protective devices like N95 masks to the list of covered countermeasures. See 42 U.S.C. § 247d-6d(i)(1)(D); see also 85 Fed. Reg. at 21,014.

47. Also, in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3103, Pub. L. No. 116-136 (March 27, 2020), the PREP Act COVID-19 declaration was amended to **add respiratory protective devices** to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.⁵ See 42 U.S.C. § § 247d, 247d-6(i)(1)(D).

48. On June 8, 2020, the Declaration was amended again to reflect the HHS’s original intent to “identify the full range of qualified countermeasures” as permitted under the PREP Act. 85 Fed. Reg. 35100. Thus, a covered countermeasure includes a broad range of products and devices specified as: (i) a qualified pandemic or epidemic product; (ii) a security countermeasure; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use; and, (iv) a NIOSH-approved respiratory protective device.

c. The PREP Act applies as there is a causal nexus between the administration or use of a covered countermeasure by a covered person

49. Immunity under the PREP Act “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution . . . **purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.**” 42 U.S.C. § 247d-6d (a)(2)(B)

50. While the term “administration” is undefined in the PREP Act, the March 17, 2020 Declaration explained that “Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and **decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients;**

management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.” 85 Fed. Reg. at 15,200. Thus, the definition of “administration” extends not only to the physical provision of a countermeasures to recipients, such as vaccinations, but also **“to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities.”**). *Id.*

51. AO 21-01 affirms that the PREP Act is triggered even in instances involving non-use or the non-administration of a covered countermeasure. The Advisory Opinion specifically notes “[p]rioritization of purposeful allocations of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act.” Furthermore, “a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure.

52. AO 21-01 further clarifies that the PREP Act would still be triggered when a facility “fails to administer [a] therapeutic...assuming the non-use of the therapeutic was the result of conscious decision-making.” However, even further, if a plaintiff alleges that the decisions surrounding the use of a therapeutic were “wanton and willful,” those matters **must** be transferred to the District Court of the District of Columbia for resolution by a three-judge panel. *See* 42 U.S.C. 247d-6d)d)-(e).

53. Even still, the Advisory Opinion further clarifies that the PREP Act should be applied to the broadest extent possible, and even in rare instances where a plaintiff argues that “defendant failed to make any decisions whatsoever,” federal courts are **“free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint.”** (citing *United*

Surgical Assistants, LLC v. Aetna Life Ins. Co., 2014 WL 4059889 at *1 (M.D. Fla. Aug. 14, 2014).

54. In the present matter, Plaintiffs' Complaint on its face alleges that the Andover facilities negligently administered and allocated PPE to individuals within the facility.

55. During the initial outbreak of COVID-19 in March 2020, the Andover facilities took proactive steps to procure PPE including facemasks, gowns, gloves, and other devices to limit the transmission and spread of COVID-19. **See attached hereto as Exhibit F, a true and accurate copy of Certifications from Sonia Velmonte & Mariusz Janik.**

56. Medical supply vendors such as Medline were frequently contacted by the facilities for additional supplies, however, in March 2020 there were severe shortages of PPE. Additionally, multiple attempts were made to secure additional resources from various government agencies.

57. In an effort to preserve PPE, Andover patients were placed in cohorts, facemask use times were extended, and facemasks were reused consistent with CDC and other guidance. Id.

58. Additionally, decisions were made to allocate PPE to staff and residents based on COVID status, exposure and work area in an effort to allocate and preserve scarce resources. Id.

59. It is therefore clear that Defendants have satisfied the threshold question provided in the most recent Advisory Opinion. Defendants did not "abdicate" their responsibilities in planning, allocating, or distributing covered countermeasures. To the contrary, Defendants made conscious and competent allocation decisions and made numerous efforts to prevent the spread of COVID-19. The actions taken by Defendants in this matter are precisely the types of actions which are to be given "sweeping" protections under the PREP Act.

II. PLAINTIFFS' CLAIMS MUST BE "RECHARACTERIZED" AS FEDERAL CLAIMS UNDER THE PREP ACT

60. The PREP Act is a complete preemption statute. The PREP Act: 1) expresses Congress's intent to broadly preempt state law claims; 2) creates an exclusive federal cause of action for injuries

caused by willful misconduct; and 3) establishes a compensation fund for injuries directly caused by the administration or use of covered countermeasures. Thus, the statute meets the test for complete preemption. Railway Labor Executives Asso. v. Pittsburgh & L. E. R. Co., 858 F.2d at 942. (3rd Cir. 1988).

61. First, the PREP Act provides broad immunity to any “covered person” with respect to all “claims for loss arising out of, relating to, or resulting from” the “administration” or “use” of a “covered countermeasure” if a declaration has been issued with respect to that countermeasure:

[A] covered person *shall be immune from suit and liability* under Federal and State law with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1) (emphasis added).⁶

62. This complete preemption provision is accompanied by additional preemption of state laws that are different from the PREP Act:

During the effective period of a declaration [by the Secretary], . . . no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure *any provision of law or legal requirement* that (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) *relates to* the . . . use, . . . dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section.

42 U.S.C. § 247d-6d(b)(8) (emphasis added).

63. Second, the PREP Act also assigns exclusive federal jurisdiction for bringing “willful misconduct” claims exclusively in the United States District Court for the District of Columbia.

42 U.S.C. § 247d-6d(e)(1).

⁶ “Loss” is broadly defined as “any type of loss,” including death, physical injury, mental injury, emotional injury, fear, property loss and damage, and business interruption loss. 42 U.S.C. § 247d-6d(a)(2)(A). Moreover, the immunity applies to any claim “that has a causal relationship with the administration to or use by an individual of a covered countermeasure.” Id. § 247d-6d(a)(2)(B).

64. Thus, by pleading that Defendants’ conduct rises to the level of willful misconduct, Plaintiffs have placed their claims exclusively in federal court, and they must be brought in the District of Columbia District Court pursuant to 42 U.S.C. § 247d-6d(e)(1).

65. Advisory Opinion 21-01 confirms without equivocation that “The Prep Act” is a “complete preemption” statute. The Act establishes a fund providing for compensation for injuries directly caused by the administration or use of covered countermeasures. The PREP Act—like the Worker’s Compensation Act and the National Vaccine Compensation Program—creates a remedy that is “exclusive of any civil action or proceeding (§ 247d-6(e)(d)(4)) for the specific purpose of serving “in place of expensive and uncertain litigation.” 42 U.S.C. § 247d-6d(a). Persons injured in circumstances implicating covered countermeasures may seek compensation by making requests for benefits under the Countermeasures Injury Compensation Program (CICP). Id. § 247d-6e.

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67. The January 8, 2021 Advisory Opinion confirms that the PREP Act is a complete preemption statute in that it establishes both a federal and administrative cause of action as the only viable claims and vests exclusive federal jurisdiction in federal court. The Fifth Amendment to the Secretary’s Declaration reiterates the complete preemption of state law based on the substantive

federal interests at stake. 86 Fed. Reg. at 7874. The statutory language, Secretary’s Declarations, and Advisory Opinions, when read together as they must be, support a finding that the PREP Act completely preempts Plaintiffs claims in this case.

68. The PREP Act’s language should be compared to that in other statutes that have been found to completely preempt state law claims. The Supreme Court has applied “complete preemption” as a basis for federal question removal in a number of cases where a federal statute provides an exclusive federal remedy and procedures and remedies governing the claim, as the PREP Act does. Indeed, the Supreme Court has found preemption in statutes containing less clear and direct language than the PREP Act.

69. For example, in Bruesewitz v. Wyeth, 562 U.S. 223 (2011), the Supreme Court held that the National Childhood Vaccine Injury Act (“NCVIA”) broadly preempts all state law claims for alleged design defects in vaccines. It is instructive that the dissent in Bruesewitz viewed the NCVIA’s preemptive effect as more limited than that in the PREP Act because the language of the NCVIA is not as clear and direct as the PREP Act’s broader preemption language:

[W]hen Congress intends to pre-empt . . . claims categorically, it does so using categorical (e.g., “all”) and/or declarative language (e.g., “shall”), rather than a conditional term (“if”). For example, . . . [w]ith respect to [the PREP Act’s] “covered countermeasure[s],” Congress provided that subject to certain exceptions, “a covered person *shall* be immune from suit and liability under Federal and State law with respect to *all* claims for loss caused by, arising out of, *relating to*, or resulting from the administration to or the use by an individual of a covered countermeasure,” §247d-6d(a)(a), . . . Id. at 253.

70. Another federal statute with a similar framework as that of the PREP Act—the Air Transportation Safety and System Stability Act (ATSSSA)—has been found to be a complete preemption statute. The ATSSSA created a Victim Compensation Fund to provide exclusive remedies for victims and their families who were killed or injured in the September 11, 2001 terrorist attacks. See 49 U.S.C. § 40101. In McNally v. Port Auth. (In re WTC Disaster Site), 414

F.3d 352 (2d Cir. 2005), the court held the preemptive language of the ATSSSA, together with the provision for the Victims Compensation Fund, demonstrated the intent to completely preempt claims sufficient to authorize removal to federal court. Id. at 375.

71. Complete preemption as a basis for federal question removal has been applied with respect to dozens of federal statutory schemes that bear strikingly similar characteristics of providing an exclusive federal remedy and procedures and remedies governing the claim as those contained in the PREP Act. See, e.g., Beneficial Nat'l Bank v. Anderson, 539 U.S. 1 (2003) (claims for usury against a national bank); In re WTC Disaster Site, 414 F.3d 352 (ATSSSA); Hoskins v. Bekins Van Lines, 343 F.3d 769 (5th Cir. 2003) (Carmack Amendment to Interstate Commerce Act); Bastien v. AT&T Wireless Servs., Inc., 205 F.3d 983 (7th Cir. 2000) (Federal Communications Act); see also 14C Charles Alan Wright et al., Federal Practice and Procedure § 3722.2, nn. 47-57 (2018) (collecting cases under various statutes).

72. In Beneficial National Bank, the Supreme Court found the National Bank Act to be completely preemptive because the statute provides for an exclusive cause of action for state usury claims. 539 U.S. at 9. So, too, does the PREP Act provide an exclusive cause of action for claims against covered persons relating to the administration or use of covered countermeasures. As in Beneficial National Bank, the PREP Act “form[s] a system of regulations,” id. at 10, for the whole-of-nation response to a public health emergency, displacing state law that differs or conflicts. The PREP Act “completely defines” a cognizable claim, id. at 10-11, and is based upon a special federal interest in providing protection to the vital private individuals and entities so crucial to the nation’s response to the COVID-19 pandemic.

73. Thus, as in Beneficial National Bank, no state law claim for loss against a covered person relating to the administration of a covered countermeasure exists under the PREP Act.

III. FEDERAL QUESTION JURISDICTION EXISTS PURSUANT TO THE GRABLE DECISION

74. The most recent Advisory Opinions issued by HHS and the Secretary’s Fourth Declaration and also support the view warranting federal jurisdiction under the embedded federal issue doctrine. Under this doctrine state law claims can give rise to federal jurisdiction when they “implicate significant federal issues.” Grable, 545 U.S. at 312.

75. The embedded federal issue doctrine “captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” Id.

76. A federal forum is also important when substantial federal question[s] of great federal interest are presented, even when raised by a complaint framed in terms of state law, provided that resolution of the federal question is necessary to the resolution of the state-law claim.” 1 Moore’s Manual--Federal Practice & Procedure § 5.10 (2020).

An issue may be substantial where the outcome of the claim could turn on a new interpretation of a federal statute or regulation which will govern a large number of cases. In other words, a case is more likely to be important to the federal system as a whole if it presents “a nearly ‘pure issue of law ... that could be settled once and for all’” rather than an issue that is “fact-bound and situation-specific” and whose holding will more likely be limited to the facts of the case.

Municipality of Mayagüez v. Corporación Para el Desarrollo del Oeste, Inc., 726 F.3d 8, 14 (1st Cir. 2013).

77. Thus, embedded federal jurisdiction may exist where “a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” Gunn v. Minton, 568 U.S. 251, 258 (2013) (citing Grable, 545 U.S. at 313-14).

78. In the context of the COVID-19 pandemic, which has affected every state in the country, the present case raises substantial questions concerning the application of various provisions of the

PREP Act, including the broad immunity provision and the interpretation of the exception for claims involving willful misconduct, as the Secretary explicitly recognized in the Fourth Declaration:

COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg., 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg., 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act.

85 Fed. Reg. at 79197.

79. The Declaration interprets the PREP Act as expressing Congress' intent for an exclusive federal forum and notes that through the PREP Act, Congress delegated to the Secretary "the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations." *Id.* at 79198. The Grable doctrine and PREP Act are therefore directly applicable to Plaintiffs' claims and support this Court's jurisdiction.
80. Further, Advisory Opinion 21-01 holds that "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means the case belongs in federal court." This interpretation is consistent with the Supreme Court's long-standing rule "that in certain cases federal question jurisdiction will lie over state-law claims that implicate federal issues." Grable at 312.
81. Here, Defendants have met the requirements warranting federal jurisdiction. First, Plaintiffs' bring claims arising from the alleged use or administration of covered countermeasures in connection with the care and treatment of the named Plaintiffs. This necessarily raises an actual

disputed issue which is critical to the outcome of this case. Furthermore, the Advisory Opinion confirms the express intention to have federal courts supersede and preempt state jurisdiction with respect to the issues raised by Plaintiffs. As such, these issues must resolved in the federal court system.

WHEREFORE, Defendants hereby notify Plaintiffs that the above-entitled action, formerly pending in the Sussex County Superior Court, has been removed from that court to this Court.

By: /s/ Malinda A. Miller
Malinda A. Miller, Esq.
S. Christopher Martino, Esq.
LEWIS BRISBOIS BISGAARD & SMITH,
LLP
*Attorneys for Defendants, Alliance HC
Holdings, LLC d/b/a Andover Subacute &
Rehabilitation I; Alliance HC II LLC d/b/a
Andover Subacute & Rehabilitation II
(Alliance Healthcare being improperly
pleaded by name and as a separate entity);
Chaim "Muttu" Scheinbaum; Louis Schwartz*

Date: February 8, 2021